May 15, 2019

K2m, Inc.
Mr. Casey Hinckley
Regulatory Affairs Specialist
600 Hope Parkway, SE
Leesburg, Virginia 20175

Re: K190584
Trade/Device Name: CAYMAN LP Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: March 5, 2019
Received: March 6, 2019

Dear Mr. Hinckley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for CAPT Raquel Peat, PhD, MPH, USPHS
Director
Office of Health Technology 6
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190584

Device Name
CAYMAN LP Plate System

Indications for Use *(Describe)*
The CAYMAN LP Plate System is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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2 510(k) Summary

510(k) Summary: CAYMAN LP Plate System	
Submitter:	K2M, Inc.
Contact Person :	Casey Hinckley Regulatory Affairs Specialist Phone: +1 (571) 919-2318 Fax: +1 (866) 466-6109 Email: casey.hinckley@stryker.com
Date Prepared:	March 5, 2019
Trade Name:	CAYMAN LP Plate System
Common Name:	Appliance, fixation, spinal intervertebral body
Proposed Class:	Class II
Classification Name:	Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060)
Product Code:	KWQ
Predicate Devices:	Primary Predicate: K2M CAYMAN Buttress Plate System (K080302) Additional Predicates: Innovasis Kestral Buttress Plate System (K181063), and Stryker LITe Plate System (K142699)
Device Description:	The CAYMAN LP Plate System are non-load bearing devices, each consisting of a plate and screw for attachment to the vertebral body. The plates are designed to be used as additions to spinal fusion procedures from the lateral and anterior approaches, forming a preventative barrier to intervertebral cage movement. Materials: The devices are manufactured from Ti6Al4V per ASTM and ISO standards. Function: The plates are designed to be used in a spinal fusion procedures to provide stabilization and buttressing of tissue in the intervertebral space.
Intended Use:	The CAYMAN LP Plate System is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications.

510(k) Summary: CAYMAN LP Plate System	
Summary of the Technological Characteristics	The CAYMAN LP Plate System is considered substantially equivalent to other legally marketed devices. They are similar in design, material, and indications for use.
Summary of the Performance Data	Nonclinical testing was performed to demonstrate that the CAYMAN LP Plate System is substantially equivalent to its predicate devices. Mechanical tests were performed to test the ability of the plates to resist migration or expulsion of the graft material.
Conclusion	The CAYMAN LP Plate System has identical indication, technological characteristics, and principles of operation as its predicates. The nonclinical test results demonstrated that the new CAYMAN LP plate is mechanically superior to the legacy CAYMAN Buttress Plate. The CAYMAN LP Plate System was shown to be substantially equivalent to its predicate devices.